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CASE 33314



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF  
WINDISCH ET AL.

INTERNATIONAL APPLICATION NO: EP/2004009067

FILED: 12 AUGUST 2004

U.S. APPLICATION NO:

35 USC §371 DATE: 13 FEBRUARY 2006

FOR: EXPRESSION VECTORS, TRANSFORMED HOST CELLS, AND  
FERMENTATION PROCESS FOR THE PREPARATION OF  
RECOMBINANT POLYPEPTIDES

**MS: Amendment**

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants believe this paper is being filed before the mailing date of a first Office action on the merits, and so under 37 C.F.R. §1.97(b)(3) no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

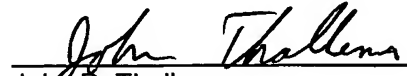
In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

These references were cited in search reports in corresponding and related applications (10/568,337, 10/568,332 & 10,568,329). Copies of these references and the search report are enclosed herewith.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
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\_\_\_\_\_  
John D. Thallemer  
Attorney for Applicants  
Reg. No. 34,940

Date: 6/30/2006

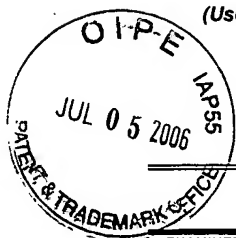
ATTY. DOCKET NO.  
33314  
APPLICATION NO.

## INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

APPLICANT  
WINDISCH ET AL.  
FILING DATE  
FEBRUARY 13, 2006

Group



## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	5,710,027	1/20/98	Hauptmann et, al			
	AB	2003/0026805	2/6/03	Athwal et,al.			
	AC	5,648,237	7/15/97	Paul J. Carter			
	AD	4,680,262	7/14/87	Bochner et, al.			
	AE	2004/151695	8/5/04	Kwon et al.			
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION YES NO	
	AM	WO 89/00201	1/12/89	University of Dundee			<input type="checkbox"/>	<input type="checkbox"/>
	AN	WO 03/004599	1/16/03	Insight strategy & Mkt Ltd			<input type="checkbox"/>	<input type="checkbox"/>
	AO	EP 0 974 654	1/26/00	Mitsui Chemicals Inc			<input type="checkbox"/>	<input type="checkbox"/>
	AP	WO 01/57217	8/9/01	Choi Ki Doo et al.			<input type="checkbox"/>	<input type="checkbox"/>
	AQ						<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	BOURDINEAUD J P ET AL: "Cytoplasmic and Periplasmic Expression of a Synthetic gene for Ferredoxin in Escherichia-coli", Biochimie (Paris), vil.72, no. 6-7, 1990, pages 407-415, XP002316190
	AS	WEICKERT M J ET, AL: "Optimization of Heterologous Protein Production in Escherichia Coli", Current opinion in Biotechnology. London, GB, Vol. 7, no. 5, 1996, pages 494-499, XP000995157
	AT	HUMPHREYS D P ET AL:"High- LEVEL Periplasmic Expression in Escherichia coli Using a Eukaryotic Signal Peptide: Importance of Codon usage at the 5' end of the coding sequence" Protein expression and purification academic press, San Diego, CA, US, Vol. 20, no.2, November 2000, pgs

EXAMINER

DATE CONSIDERED

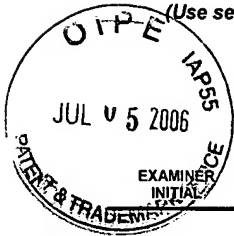
\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.

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Group



## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

DA	MATSUDA A ET AL: " Molecular Cloning and Structure of the Gene for 7-beta-4 Carboxybutanamidocephalosporanic-acid acylase from a pseudomonas strain", Journal of Bacteriology, vol. 163, no. 3, 1985, pages 1222-1228, XP002316191
DB	FRENCH C ET AL: " Development of a simple method for the recovery of recombinant proteins from the escherichia coli periplasm" Enzyme and Microbial Technology, Stoneham, MA, US, Vol. 19, no. 5, 1996, pages 332-338, XP000886796
DC	DALMORA S ET AL: " Analysis of recombinant human growth hormone directly in osmotic shock fluids" Journal of Chromatography A, Elsevier Science, NL., Vol. 782, no. 2, 10 October 1997, pages 199-210, XP004096275
DD	ANDERSON D C ET AL: " Production technologies for monoclonal antibodies and their fragments", Current opinion in Biotechnology, Vol 15, No. 5, October 2004, Pages 456-462
DE	DE OLIVEIRA J E ET AL: " High-yield purification of biosynthetic human growth hormone secreted in Escherichia coli periplasmic space" Journal of Chromatography A, Elsevier Science, NL. Vol. 852, no. 2, 13 Aug 1999, pages 441-450
DF	HANNIG G ET AL: " Strategies for optimizing heterologous protein expression in Escherichia coli", Trends in Biotechnology, Vol. 16, no. 2., February 1998, pages 54-60, XP004107042
DG	MIDDLEBERG A P J: "Process-scale disruption of microorganisms" Biotechnology Advances, Vol. 13, no. 3, 1995, pages 491-551, XP004045404
DH	BANEYX F: "Recombinant protein expression in Escherichia coli" current opinion in Biotechnology, vol 10, no. 5, October 1999, pages 411-421, XP001041299
DI	HART R A ET AL: "Large scale, in situ isolation of periplasmic IGF-I from E. Coli", Bio Technology, Vol. 12, November 1994, pages 1113-1117, XP001153305
DJ	
DK	
DL	
DM	
DN	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial of reference considered, whether or not citation is in conformance with MPEP 609: Draw a line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.